

WHAT IS CLAIMED IS:

5           1. A pharmaceutical suspension formulation  
suitable for aerosol administration, consisting  
essentially of a therapeutically effective amount of a  
drug and a propellant selected from the group  
consisting of HFC 134a, HFC 227, and a mixture thereof,  
10 the formulation being further characterized in that it  
exhibits substantially no growth in particle size or  
change in crystal morphology of the drug over a  
prolonged period, is substantially and readily  
redispersible, and upon redispersion does not  
15 flocculate so quickly as to prevent reproducible dosing  
of the drug.

          2. A formulation according to Claim 1,  
wherein the propellant is a mixture of HFC 134a and HFC  
20 227.

          3. A formulation according to Claim 1,  
wherein the propellant is HFC 227.

25           4. A formulation according to Claim 1,  
wherein the propellant is HFC 134a.

          5. A formulation according to Claim 1,  
wherein the drug concentration is less than about 0.1  
30 percent.

          6. A formulation according to Claim 1,  
wherein the drug concentration is greater than about  
0.1 percent and less than about 0.5 percent.  
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          7. A formulation according to Claim 1,  
wherein the drug concentration is greater than about  
0.5 percent.

8. A formulation according to Claim 1,  
wherein the drug has a potency such that a  
concentration of less than about 0.1 percent is  
5 therapeutically effective.

9. A formulation according to Claim 1,  
wherein the drug is selected from the group consisting  
of formoterol, salmeterol, and a pharmaceutically  
10 acceptable salt thereof.

10. A formulation according to Claim 1,  
wherein the drug is formoterol fumarate.

15 11. A formulation according to Claim 10,  
wherein the formoterol fumarate is present in an amount  
of about 0.01 percent to about 0.10 percent.

12. A formulation according to Claim 11  
20 wherein the formoterol fumarate is present in an amount  
of about 0.02 percent.

13. A formulation according to Claim 11,  
wherein the propellant is HFC 134a.  
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14. A formulation according to Claim 11,  
wherein the propellant is HFC 227.

15. A formulation according to Claim 12,  
30 wherein the propellant is HFC 134a.

16. A formulation according to Claim 1,  
wherein the drug is selected from the group consisting  
of albuterol, beclomethasone dipropionate, cromolyn,  
35 pirbuterol, and a pharmaceutically acceptable salt or  
solvate thereof.

17. A formulation according to Claim 1, wherein the drug is selected from the group consisting of albuterol sulfate, disodium cromoglycate, and pirbuterol acetate.

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18. A formulation according to Claim 5, wherein the drug is selected from the group consisting of beclomethasone dipropionate, albuterol, formoterol, and pirbuterol, and a pharmaceutically acceptable salt or solvate thereof.

19. A formulation according to Claim 4, wherein the drug is selected from the group consisting of beclomethasone dipropionate, albuterol, formoterol, and pirbuterol, and a pharmaceutically acceptable salt or solvate thereof, and wherein the drug is present in an amount of greater than about 1.6 percent.

20. A formulation according to Claim 3, wherein the drug is disodium cromoglycate, and the drug is present in an amount of less than about 0.1 percent.

21. A formulation according to Claim 3, wherein the drug is disodium cromoglycate, and the drug is present in an amount greater than about 1.4 percent.

22. A formulation according to Claim 2, wherein the drug is formoterol fumarate.

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23. A formulation according to Claim 22, wherein the mixture contains substantially equal amounts of HFC 134a and HFC 227.

24. A formulation according to Claim 2, wherein the drug is beclomethasone dipropionate or a pharmaceutically acceptable solvate thereof.

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25. A formulation according to Claim 24, wherein the mixture contains substantially equal amounts of HFC 134a and HFC 227.

5           26. A formulation according to Claim 5, wherein the drug is salmeterol.

          27. An aerosol canister containing a formulation according to Claim 1 in an amount  
10 sufficient to provide a plurality of therapeutically effective doses of the drug.

          28. A metered dose aerosol canister containing a formulation according to Claim 1 in an  
15 amount sufficient to provide a plurality of therapeutically effective doses of the drug.

          29. A method of preparing a formulation according to Claim 1, comprising the steps of: (i)  
20 combining an amount of the drug sufficient to provide a plurality of therapeutically effective doses and a propellant selected from the group consisting of HFC 134a, HFC 227, and a mixture thereof in an amount sufficient to propel from an aerosol canister a  
25 plurality of therapeutically effective doses of the drug; and (ii) dispersing the drug in the propellant.

          30. A method of treating a mammal having a condition capable of treatment by inhalation,  
30 comprising the step of administering by inhalation a formulation according to Claim 1 to the mammal.

          31. A suspension aerosol formulation comprising a therapeutically effective amount of  
35 micronized drug selected from the group consisting of pirbuterol acetate and pirbuterol hydrochloride, and a propellant comprising HFC 227 the formulation being

further characterized in that it is substantially free of perfluorinated surfactant.

32. A formulation according to Claim 31,  
5 wherein the drug is pirbuterol acetate.

33. A formulation according to Claim 32,  
containing about 0.4 to about 1.0 percent by weight  
pirbuterol acetate.

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34. A formulation according to Claim 32,  
containing about 0.45 to about 0.9 percent by weight  
pirbuterol acetate.

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35. A formulation according to Claim 32,  
wherein HFC 227 is substantially the only propellant.

36. A formulation according to Claim 35,  
substantially free of ethanol.

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37. A formulation according to Claim 32,  
further comprising about 0.1 to about 12 percent by  
weight ethanol.

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38. A formulation according to Claim 32,  
further comprising about 2 to about 8 percent by weight  
ethanol.

39. A formulation according to Claim 32,  
30 further comprising about 5 to about 12 percent by  
weight ethanol.

40. A formulation according to Claim 37,  
further comprising about 0.01 to about 0.5 percent by  
35 weight oleic acid.

41. A formulation according to Claim 32, consisting essentially of HFC 227 and a therapeutically effective amount of pirbuterol acetate.

5           42. A formulation according to Claim 41, wherein the pirbuterol acetate is present in an amount of about 0.4 to about 1.0 percent by weight.

10           43. A formulation according to Claim 32, consisting essentially of a therapeutically effective amount of pirbuterol acetate, about 5 to about 12 percent by weight ethanol, and HFC 227.

15           44. A method for inducing bronchodilation in a mammal, comprising the step of administering by inhalation to the lung of the mammal an amount of a formulation according to Claim 32 effective to induce bronchodilation.

20           45. A method of preparing a formulation according to Claim 32, comprising the steps of:  
            (i) combining the micronized pirbuterol acetate with the propellant; and  
            (ii) dispersing the pirbuterol acetate in the  
25                       propellant.

46. A formulation according to Claim 32 in an aerosol vial equipped with a metered dose valve.

30           47. A suspension aerosol formulation comprising a therapeutically effective amount of micronized albuterol sulfate and HFC 227 as substantially the only propellant.

35           48. A formulation according to Claim 47 wherein the micronized albuterol sulfate is present in an amount of about 0.2 to about 0.5 percent by weight.

49. A formulation according to Claim 47, wherein said formulation is substantially free of perfluorinated surfactant.

5 50. A formulation according to Claim 47 further comprising from about 0.1 to about 20 percent by weight of ethanol.

10 51. A formulation according to Claim 50, wherein said ethanol is present in an amount of about 5 to about 15 percent by weight.

15 52. A formulation according to Claim 51 further comprising from about 0.01 to about 0.5 percent by weight of a surfactant selected from the group consisting of oleic acid and sorbitan trioleate.

20 53. A formulation according to Claim 52, wherein said surfactant is oleic acid.

54. A formulation according to Claim 52, wherein said surfactant is sorbitan trioleate.

25 55. A formulation according to Claim 47 consisting essentially of about 0.2 to about 0.5 percent by weight of micronized albuterol sulfate and HFC 227.

30 56. A formulation according to Claim 47 consisting essentially of about 0.35 to about 0.42 percent by weight of micronized albuterol sulfate and HFC 227.

35 57. A formulation according to Claim 51 consisting essentially of about 0.2 to about 0.5 percent by weight of micronized albuterol sulfate, about 5 to about 15 percent by weight of ethanol, and HFC 227.

58. A method for inducing bronchodilation in a mammal comprising the step of administering by inhalation to the lung of the mammal an amount of a formulation according to Claim 47 effective to induce  
5 bronchodilation.

59. A method of preparing a formulation according to Claim 47, comprising the steps of:  
10 (i) combining the micronized albuterol sulfate with the propellant; and  
(ii) dispersing the albuterol sulfate in the propellant.

60. A formulation according to Claim 47 in  
15 an aerosol vial equipped with a metered dose valve.